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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,360	11/18/2003	Robert J. Thomas	1440.2032-001	6678
21005 7590 03/17/2010 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				
EXAMINER				
PATEL, NIHIR B				
ART UNIT		PAPER NUMBER		
3772				
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03/17/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/716,360

**Applicant(s)**

THOMAS ET AL.

**Examiner**

NIHIR PATEL

**Art Unit**

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on amendment filed on September 17<sup>th</sup>, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 13-68 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 10-12 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 69, 70, 73 and 75 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 7, 71, 72, 74, 76 and 77 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

#### *Response to Arguments*

1. Applicant's arguments filed on September 17<sup>th</sup>, 2009, with respect to claims 1-8 and 10-12 have been fully considered and are persuasive. The previous rejection(s) of the office action dated June 19<sup>th</sup>, 2009 has been withdrawn.

#### *Response to Amendment*

2. The examiner acknowledges the amendment filed on September 17<sup>th</sup>, 2009. The amendment comprises adding new claims 69-77.

#### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims **1-3, 6, 69, 70, 73 and 75** are rejected under 35 U.S.C. 102(b) as being anticipated by Tham et al. (US 5,957,129).

5. **As to claim 1**, Tham teaches an apparatus that comprises a PAP device **10** for sleep therapy **(the phrase sleep therapy is a broad term and the fact the patient remains unconscious (see col. 1 lines 15-25) is defined as sleep therapy)**, the PAP device further comprises a source of medical grade carbon dioxide **45 (see col. 6 lines 15-25)**; an assembly for combining pressurized air from the PAP device **(see col. 6 lines 14-25)**, with substantially low

concentration of the medical grade carbon dioxide resulting in a gas mix (see col. 6 lines 14-25); and a patient centric ventilatory space module coupled to the assembly providing the resulting gas mix for inhalation by a given target, the inhalation of the gas effecting respiratory stability of the target (see col. 5 lines 60-65).

6. **As to claim 2**, Tham teaches an apparatus wherein the assembly includes a sensor 60 for measuring air flow (see col. 7 lines 5-10).

7. **As to claim 3**, Tham teaches an apparatus wherein the PCVSM includes any of face mask and a nasal cannula (see col. 5 lines 60-65).

8. **As to claim 6**, Tham teaches an apparatus wherein at least one of the source, the assembly and the PCVSM is computer processor 48 controlled to modulate concentration of carbon dioxide in the gas mix (see col. 6 lines 20-30).

9. **As to claim 69**, Tham teaches an apparatus that comprises a source of medical grade carbon dioxide 45 (see col. 6 lines 15-25); an assembly for combining pressurized air from a positive airway pressure PAP device 4 with substantially low concentrations of the medical grade carbon dioxide resulting in a gas mix (see col. 6 lines 14-25); and a patient centric ventilatory space module (PCVSM) 16 (see col. 5 lines 60-65) coupled to the assembly providing the resulting gas mix for inhalation by a given target, said inhalation of the gas mix effecting respiratory stability of said target (see col. 6 lines 30-36).

10. **As to claim 70**, Tham teaches an apparatus wherein at least one of the source, the assembly and the PCVSM is computer processor controlled to modulate concentration of carbon dioxide in the gas mix (see col. 6 lines 14-25 and col. 7 lines 5-15).

11. **As to claim 73**, Tham teaches an apparatus that comprises a sensor wherein the computer processor determines from a signal from the sensor concentration of CO<sub>2</sub> in a patient's end tidal breath (see col. 7 lines 5-15).

12. **As to claim 75**, Tham teaches an apparatus wherein the source of the carbon dioxide is a pressurized source (see col. 6 lines 15-25); and the gas concentration system further comprise a control valve module which regulates flow of the carbon dioxide from the pressurized source to the assembly, the control valve module responding to a control signal from the computer processor (see col. 6 lines 15-35).

*Allowable Subject Matter*

13. Claims **8 and 10-12** are allowed. The prior art does not teach a method for preparing a gas mix for enabling respiratory stability for a positive air way pressure device for sleep therapy comprising the steps of providing a substantially low concentration of medical grade carbon dioxide to a PAP device used for sleep therapy.

14. Claims **4 and 5** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach providing concentration of carbon dioxide in the gas mixture that is between 0.5% and about 1.25%.

15. Claims **7, 71, 72, 74, 76 and 77** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach the computer processor modulates concentration of carbon dioxide in the gas mix as a function of any combination of

sensed concentration of carbon dioxide in the PCVSM, sensed target state and detected system changes.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/  
Examiner, Art Unit 3772

/Patricia Bianco/

Application/Control Number: 10/716,360

Page 6

Art Unit: 3772

Supervisory Patent Examiner, Art Unit 3772